REMARKS

The amendment to the Cross-Reference section corrects and updates the priority claim.

No changes have been made in the claims. Claims 22-32 and 34-35 remain in the application originally presented in the Preliminary Amendment filed October 26, 1999.

In the Final Action mailed October 26, 2003, the Examiner maintains the rejection of claims 22-32, and 34-35 as unsupported by the written description as filed unless a new declaration identifying the present application as a continuation-in-part of its immediate parent is filed, and also maintains the rejection of claims 22-32 and 34-35 as anticipated by Roubin, et al, US 5,827,321, filed Feb. 7, 1997.

In particular, the Examiner maintains that the priority applications did not contemplate presetting the elasticity to elongate as presently recited in claim 22 and maintains that the stent of Figures 11a and 11b is not taught to be made of nitinol. As understood, the same objection is the basis for both the written description rejection and the Examiner's refusal to credit the claims with benefit of at least the immediate parent's priority date of May 18, 1995. The rejections are again traversed on the ground that the rejected claims are clearly supported by the application and claims, as filed before the preliminary amendment, and as such are entitled to benefit of the PCT filing date of the applicant's parent application. Therefore there is no new matter requiring a new declaration and Roubin et al is not a prior art document.

Preparatory to filing an appeal on this matter, file has been carefully reviewed. It is observed that, while the applicant's position on these matters has been well and frequently articulated, and the relevant disclosure has been referenced, it has not been spelled out in a logical sequence which demonstrates compellingly that claim 22 is fully supported prior to its filing in the preliminary amendment. In the hope that the Examiner may yet be persuaded to correct his error, the following detailed analysis of the application support for the disputed recitations in claim 22 is provided. Reconsideration on the basis thereof is requested.

In the comments below, citations in brackets are to the application as filed before the preliminary amendment (corresponding to the text of the PCT parent application and therefore entitled to a priority date of May 18, 1995, more than 20 months prior to the §102(e) date of the Roubin et al patent).

I. Preset Elasticity of the Fig 11 Stent

The specification, and claims, describe stents which have 1) a ***deployable*** diameter at less than body temperature, 2) an ***expanded*** diameter larger than the deployable diameter, to which the stent self-expands at body temperature, and a "larger desired expanded" size or "***enlarged***" diameter[1] to which the stents may further expand by application of a deformation force (for instance using a balloon) [page 2, lines 5-9, and each original independent claim]. These are characteristics generally of the stents of the invention. Therefore, a statement in the specification that a particular figure depicts a stent of the invention is an express teaching that such stents have these characteristics.

Figures 8-11 depict stents of the invention [page 12, lines 14-16]. As such they are to be understood as having "deployable," "expanded" and "enlarged" diameter configurations.

The application uses the terms "compressed," "constrained," and "deformed to a small diameter" to describe the stent configured at the deployable diameter. In connection with Figures 8-11, the skilled person will readily recognize that this corresponds to the "closed" stents of Figures 8a, 9a, 10a, and 11a, respectively.

The application teaches that the Figures 8b, 9b, 10b and 11b, depict "expanded" configurations of the stents of Figures 8a, 9a, 10a, and 11a, respectively. Since the "expanded" configuration is the configuration of the stents after self-expansion and before balloon deformation, Figure 11b, in particular, is the configuration of the stent of Figure 11a to which the stent self-expands. Moreover, since Figure 11b is not described as depicting a "larger desired expanded" or an "enlarged", configuration, it is ***not*** the configuration the stent is still capable of adopting due to balloon deformation.

Self-expansion is caused by a shape memory characteristic built into the stent by various fabrication and manipulation techniques. Shape memory is an elasticity property. With respect to Figure 11a, the stent is preset to self-expand to the configuration of Figure 11b. Thus the patent teaches that the material of the stents of the invention have a ***preset elasticity*** which causes the stent to assume the configuration to which it self-expands. Since Figure 11b depicts the condition to which the stent of Figure 11a self-expands, the stent of Figure 11a has a preset elasticity to assume the condition of Figure 11b.

---

1 The claims use the "***enlarged***" diameter term and, for brevity, we do the same from here-on-out.

The preset elasticity of the stent of Figure 11a causes the longitudinal length of the radial bands to decrease and the longitudinal length of the connector to increase. This "necessarily" results from the basic geometry changes which occur as the stent transitions from Figures 11a to 11b:

Fig. 11a

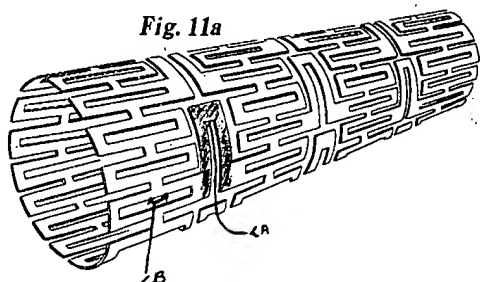
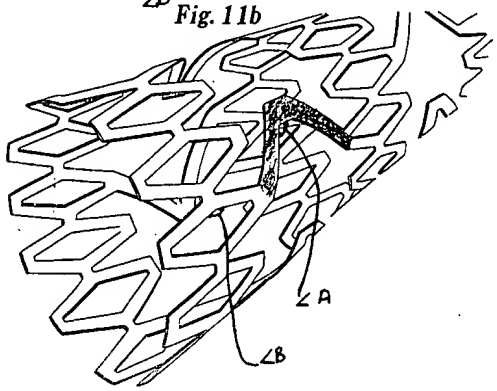


Fig. 11b



In particular, in the Figures above, where one of the relevant connectors has been highlighted with shading, because the angle <A enlarges from Fig 11a to 11b, the total longitudinal length of the connector is longer in Figure 11b. Conversely, because the angle <B in the adjacent annular element decreases, from Fig. 11a to Fig. 11b, the longitudinal length of the annular elements necessarily decreases. This is fully evident on the figures themselves. Hence the preset elasticity in the stent of Figure 11a includes a preset elasticity in the connecting member "which causes the connector to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state."

For the reasons just given, Figures 11a and 11b, taken together with the specification disclosure pertaining thereto, teach a stent which fully supports the "preset elasticity" recitation in claim 22.

II. The Fig 11 Stent - Made of Nitinol

The preferred stent material is nitinol [page 2, lines 20-22]. Each original independent claim falls into at least one of the following categories:

i) it directly recites nitinol (nickel-titanium alloy) [claims 16 and 20],

ii) it has a dependent claim which directly recites nitinol [claim 17, dependent 18],

iii) it directly recites austenite and martensite phase properties which the application teaches may be provided with nitinol [claims 9, 15, 17, 21]; or,

iv) it has a dependent claim which directly recites austenite and martensite phase properties which the application teaches may be provided with nitinol [claim 1, dependent 6].

Preferred nitinol alloys are taught, as well as methods for manipulating the nitinol stent material after fabrication of the stent, so as to provide the self-expanded configuration with the intermediate size characteristic of the "expanded" configuration [see page 5, lines 17-20, page 8, line 27 - page 9, line 8]. Nitinol is described as preferred in connection with both the embodiments of the invention employing two-discrete components [e.g. page 7, lines 7-9]. It is also the only specific material discussed in connection with the non-discrete embodiments of the invention which utilize two-phases of an alloy [pages 10-12]. At least for these reasons, the skilled person reading the application will have no doubt that the stents of Figures 8-11, may be made of nitinol.

Furthermore, the description of Figures 8-11 immediately follows description of embodiments in which nitinol exists in two phases, but without discrete components for each phase. In discussion of embodiments employing two discrete components, corresponding Figures are provided in which the discrete components are shown and labeled. None of Figures 8-11 describe, label, or appear on their face, to show two components in this manner. These additional factors further guide the skilled person to a specific and certain understanding that the stents of Figures 8-11 are examples of stent configurations which can be fashioned of nitinol according to the discussion of the non-discrete, two-phase alloy embodiments on pages 10-12. As to these embodiments, nitinol alloys are the only embodiments specifically exemplified. Therefore there is no doubt that the application is intended to teach that stents prepared in accordance therewith can be prepared using nitinol.

III Supporting Evidence

The Declaration of Dr. Kaushik Bhattacharya, Professor of Mechanics and Materials at California Institute of Technology, provides confirmatory evidence that a technically skilled person understands the application to teach the specific preset elasticity and nitinol features recited in claim 22. Such testimony is addressed to the understanding of the skilled person in a particular field as to which he has specific and specialized factual knowledge. Contrary to the assertions in the Official Action, the declaration, at paragraph 3, does state the factual basis for Dr. Bhattacharya's conclusions. Dr. Bhattacharya reviews the stent of Figures 11a and 11b in light of the inventive concepts disclosed in the application and goes to the remainder of the application to determine that those Figures refer to nitinol stents with self-expanding properties corresponding to the a preset elasticity.

As we have meticulously demonstrated in parts *I* and *II* above, there is a compelling basis in the application for the conclusions which Dr. Bhattacharya reached. The Examiner has no justifiable reason to disregard Dr. Bhattacharya's testimony.

IV The Examiner's Arguments

Against this support, the Examiner argues that the stent of Figs. 11a and 11b may have been expanded in some way other than by self expansion and/or that it may be made out of material other than nitinol.

The Examiner's assertion that the transition from Figure 11a to 11b may be the result of some force other than a preset elasticity is incorrect. Unlike Dr. Bhattacharya, the Examiner reads the description of Figures 11a and 11b as independent from the rest of the disclosure and original claims (see item (4) pages 4-6 of the Final Action). This reading directly contradicts the express disclosure that these Figures depict configurations which may be used in practicing the invention.

The application specifically teaches that the "expanded" configuration of the inventive balloons is the state to which the inventive stents self-expand. The stent of Fig 11b is a stent, of the invention, and in the "expanded" configuration. Therefore it is at the configuration to which it self-expands from the configuration of Figure 11a. This is straight-forward, elementary, logic.

The Examiner is simply wrong in suggesting Figure 11b might be understood as representing a condition reached by some other means.

The other assertion, that materials other than nitinol can be used to prepare stent of Figures 11a and 11b, is simply irrelevant to the question of support for claim 22. As we have already shown, the specification teaches the skilled person that the stent of Figs 11a and 11b can be made of nitinol at least by the two-phase, non-discrete embodiments discussed on pages 10-12. Such is the only teaching that needs to be considered for support for the recitation of nitinol in claim 22.

It is not reasonable to assert that a skilled person reading the specification as a whole would have any question whether the application's clear and repeatedly stated preference for nitinol, is applicable to the stent of Figures 11a and 11b, simply because the stent might also be prepared using other materials. Nitinol is taught in the application to be generally useful in the invention. It is the only material which the application teaches as exemplary of a recitation found in at least one claim of each claim set of the originally filed claims (*i.e.* a recitation found in each independent claim or in at least one or its dependents). By this method, nitinol is clearly taught as useful in practicing the invention as recited in each of the original independent claims in this application. The existence of alternative materials for some of the disclosed embodiments does not logically detract from the generality of the application's teachings as to the utility of nitinol. Hence, even if the skilled person were, hypothetically, to be confused as to whether the teachings of the non-discrete, two-phase alloy, embodiments were specifically applicable to Figure 11a and 11b, there still would no reasonable basis to question the applicability of the application's teachings regarding the utility of nitinol in fabricating a stent of Figures 11a and 11b.

For the reasons just given, the Examiner's arguments are inadequate to support the outstanding rejections.

V. Conclusion

Support for claim 22 in the text of the application as filed in the parent PCT/§371 application 08/737,492 filed May 18, 1995, more than 20 months prior to the §102(e) date of the Roubin et al patent. Therefore the written description rejection under 35 USC §112 should be withdrawn. The demonstrated support gives application a priority date for long before the

Roubin filing date. Therefore Roubin et al is not a proper reference under 35 USC §102(e) and the anticipation rejection under that statute should also be withdrawn. Accordingly the application is seen to be in condition for issuance of a declaration of interference with the Roubin et al patent, as originally requested in the preliminary amendment filed in this case on October 26, 1999.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: 1/19/2004 By: _____

Walter J. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\wjs\04944us04_amd_20040114.doc